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Susan Mosier, MD, Secretary

Sam Brownback, Governor

Drug Utilization Review Board
Meeting Agenda, Open Session
October 12, 2016 10:00 a.m. – 2:00 p.m.

Meeting Location
HP Enterprise Services, Building #283, Capital Room
6511 SE Forbes Ave, Topeka, KS 66619

Board Members

Lauren Morton, PharmD, BCPS	Roger Unruh, DO
James Backes, PharmD	Moneeshindra Mittal, MD
Tim Heston, DO	Judy McDaniel Dowd, PA-C
John Kollhoff, PharmD	LaTonyua Rice, PharmD, CGP

KDHE-DHCF Staff

Annette Grant, RPh	Carol Arace, Administrative Assistant

HP Enterprise Services/HID Staff

Ariane Casey, PharmD	Karen Kluczykowski, RPh
Nancy Perry, RN	Rachel Boyer, PharmD, BCPS

MCO Staff

Jonalan Smith, PharmD, FASCP, **Sunflower State Health Plan**
Jennifer Murff, RPh, **UnitedHealthcare Community Plan**
Lisa Todd, RPh, **Amerigroup**

I. CALL TO ORDER

A. Announcements

II. OLD BUSINESS

A. Review and Approval of July 13, 2016 Meeting Minutes

III. NEW BUSINESS

A. Revised Prior Authorization (PA) Criteria

1. **Enbrel (Erelzi® [etanercept-szzs])**
   Erelzi is a biosimilar agent to Enbrel. Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Prior authorization criteria for this agent was last revised in April 2016. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Erelzi.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

2. **Neupogen (Zarxio® [filgrastim-sndz])**
   Zarzio is a biosimilar agent to Neupogen. Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Prior authorization criteria for this agent was last revised in July 2014. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Zarxio.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

3. **Viekira Pak (Viekira XR® [dasabuvir/ombitasvir/paritaprevir/ritonavir])**
   Viekira XR is a 4-drug fixed-dose combination, extended-release tablet. Prior authorization criteria for this combination Hepatitis C treatment kit were last revised in January 2016. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Viekira XR.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

4. **Marinol (Syndros® [dronabinol])**
   Syndros is an oral solution formulation of Marinol. Prior authorization criteria for Marinol were last revised in July 2013. Since that time, a new agent has been approved. The prior authorization criteria is being revised to include the new agent, Syndros.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

5. **Long-Acting Opioid Dose Optimization (Troxyca ER® [oxycodone ER])**
   Troxyca ER is an opioid agonist indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Prior authorization quantity criteria for these opiate agents were last revised in October 2015. Since that time, a new agent have been approved. The prior authorization criteria is being revised to include the new agent, Troxyca ER and change quantity limits before a PA is required.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

6. **Berinert® (C1 esterase inhibitor, human)**
   Berinert is a protein C1 inhibitor indicated for the acute treatment of hereditary angioedema (HAE) attacks. Prior authorization criteria were last revised in January 2016. Since that time, it has become approved in pediatrics at least 6 years of age. The prior authorization criteria is being revised to include ages 6-12 years.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Xolair® (omalizumab)**
   Xolair is a monoclonal antibody indicated for the treatment of persistent asthma and chronic idiopathic urticaria. Prior authorization criteria were last revised in October 2014. Since that time, it has become approved in pediatrics at least 6 years of age for the maintenance treatment of asthma. The prior authorization criteria is being revised to include ages 6-12 years for this indication.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Tecfidera® (dimethyl fumarate)**
   Tecfidera is an immunomodulator indicated for the treatment of relapsing forms of multiple sclerosis (MS). The prior authorization criteria is being revised to correct the dosing regimen.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

9. **Probuphine® (buprenorphine implant)**
   Probuphine is a partial opioid agonist indicated for the maintenance treatment of opioid dependence in patients who have achieved and sustained prolonged clinical stability on low-to-moderate doses of a transmucosal buprenorphine containing product (i.e., doses of no more than 8 mg per day of Subutex or Suboxone sublingual tablet or generic equivalent). Prior authorization criteria were initially approved in July 2016. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
   i. Revised PA Criteria
   ii. *Public Comment
   iii. Board Discussion

10. **Humira® (adalimumab) [Amjevita (adalimumab-atto)]**
    Humira is a biologic agent. Prior authorization criteria were last revised in April 2016. Since that time, Humira has become indicated for the treatment of non-infectious intermediate, posterior and panuveitis. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use. Since that time, a new agent has been approved. The prior authorization criteria is also being revised to include the new agent, Amjevita.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

11. **Opdivo® (nivolumab)**
    Opdivo is an antineoplastic monoclonal antibody. Prior authorization criteria were last revised in April 2016. Since that time, Opdivo has become indicated for the treatment of Classical Hodgkin lymphoma in patients who has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

12. **Botulinum Toxins (Dysport® [abobotulinumtoxinA], Botox® [onabotulinumtoxinA])**
    Dysport and Botox are botulinum toxins. Prior authorization criteria were last revised in July 2016. Since that time, Dysport has become indicated for the treatment of lower limb spasticity. Step therapy for Botox is being proposed for the indications of migraines and overactive bladder. The prior authorization criteria are being revised to be consistent with similar agents and ensure appropriate and cost-effective use.
    i. Revised PA Criteria
    ii. *Public Comment
    iii. Board Discussion

13. **Constipation Agents (Amitiza® [lubiprostone], Linzess® [linaclotide])**
    Step therapy for anti-constipation products is being proposed to ensure cost-effective use.
    i. Prior Authorization Criteria
    ii. *Public Comment
    iii. Board Discussion

14. **Entyvio® (vedolizumab)**
    Step therapy for Entyvio is being proposed to ensure cost-effective use.
        i. Prior Authorization Criteria
        ii. *Public Comment
        iii. Board Discussion

15. **Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor Combinations (Invokamet® [Canagliflozin/metformin], Xigduo XR® [dapagliflozin/metformin], Glyxambi® [empagliflozin/linagliptin], Synjardy® [empagliflozin/metformin])**
    Step therapy for Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitor combinations is being proposed to ensure cost-effective use.
        i. Prior Authorization Criteria
        ii. *Public Comment
        iii. Board Discussion

B. New Prior Authorization (PA) Criteria

1. **Beta-Blocker/Angiotensin II Receptor Blockers Combinations (Byvalson® [nebivolol/valsartan])**
    Step therapy for Beta-Blocker/Angiotensin II Receptor combination products is being proposed to ensure cost-effective use.
        i. Prior Authorization Criteria
        ii. *Public Comment
        iii. Board Discussion

2. **Dipeptidyl Peptidase-4 (DPP-IV) Inhibitor Combinations (Kazano® [alogliptin/metformin], Oseni® [alogliptin/pioglitazone], Jentadueto®, Jentadueto XR® [linagliptin/metformin], Janumet®, Janumet XR® [sitagliptin/metformin], Kombiglyze XR® [saxagliptin/metformin])**
    Step therapy for Dipeptidyl Peptidase-4 (DPP-IV) Inhibitor Combinations products is being proposed to ensure cost-effective use.
        i. Prior Authorization Criteria
        ii. *Public Comment
        iii. Board Discussion

3. **Intranasal Antihistamine/Corticosteroid Agents (Dymista® [Azelastine/fluticasone])**
    Step therapy for intranasal antihistamine/corticosteroid products is being proposed to ensure cost-effective use.
        i. Prior Authorization Criteria
        ii. *Public Comment
        iii. Board Discussion

4. **NSAID plus PPI/H2 Blocking Agents (Duexis® [ibuprofen/famotidine], Vimovo® [naproxen/esomeprazole])**
    Step therapy for NSAID plus PPI/H2 blocking agents is being proposed to ensure cost-effective use.
        i. Prior Authorization Criteria
        ii. *Public Comment
        iii. Board Discussion

5. **Adlyxin® (lixisenatide)**
    Adlyxin is a Glucagon-Like Peptide 1 (GLP-1) Receptor Agonist indicated for the treatment of type 2 diabetes mellitus (noninsulin dependent, NIDDM) to improve glycemic control in adult patients as an adjunct to diet and exercise. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
        i. Prior Authorization Criteria
        ii. *Public Comment
        iii. Board Discussion

6. **Keytruda® (pembrolizumab)**
   Keytruda is an immunomodulator indicated for the treatment of unresectable or metastatic melanoma, metastatic non-small cell lung cancer (NSCLC), and recurrent or metastatic squamous cell carcinoma of the head and neck. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

7. **Tecentriq® (atezolizumab)**
   Tecentriq is an antineoplastic monoclonal antibody indicated for the treatment of locally advanced or metastatic urothelial carcinoma in patients who have disease progression during or following platinum-containing chemotherapy, or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

8. **Xiidra® (lifitegrast)**
   Xiidra is an ophthalmic lymphocyte function-associated antigen-1 (LFA-1) antagonist indicated for the treatment of the signs and symptoms of dry eye disease (DED). Prior authorization criteria is being proposed to ensure appropriate use based upon the FDA-approved labeling information and to remain consistent with other agents used for the approved indication.
   i. Prior Authorization Criteria
   ii. *Public Comment
   iii. Board Discussion

C. Miscellaneous Items

1. **Fee-for-Service Annual Program Assessment**
   The annual program assessment for the Medicaid fee-for-service population will be presented to show drug trends over the past state fiscal year.
   i. Presentation
   ii. Board Discussion

IV. OPEN PUBLIC COMMENT

V. ADJOURN

Lunch will be provided for the DUR Board members.
The next DUR Board meeting is scheduled for January 11, 2017.

*Public comment is limited to five minutes per product; additional time will be allowed at the DUR Board's discretion. Informal comments will be accepted from members of the audience at various points in the agenda.

****THIS AGENDA IS SUBJECT TO CHANGE****